

T-13011/4/2012-CC&V
Government of India
Ministry of Health & Family Welfare
Immunization Division

Nirman Bhawan, New Delhi
Dated: 15th February, 2013

To,
Mission Director (NRHM),
All States and UTs,

Subject: Open Vial Policy for DPT, TT, Hepatitis B, Oral Polio and Liquid Pentavalent vaccine

Sir/Madam,

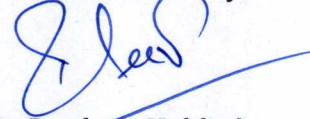
You are aware that under the Universal Immunization Programme (UIP), Government of India supplies vaccines in multi-dose vials to all States/UTs. It has been observed and also supported by recent study on vaccine wastage that some proportion of doses from the multi-dose vial gets wasted as there is no re-use policy for an opened vial.

The matter of optimal vaccine utilization was examined it has been decided to implement open vial policy for DPT, TT, Hepatitis B, Polio and Liquid Pentavalent (where applicable) currently used under the National immunization program to reduced wastage for all immunization session.

Please find enclosed the detail guidelines for use of Open Vial Policy. There will be no open vial policy for BCG, Measles and JE vaccine and the vial needs to be discarded after 4 hours of reconstitution for BCG and Measles and 2 hours for JE vaccine.

Kindly ensure that open vial policy is widely circulated and implemented. All stake holders including immunization service provider are trained as per the guideline.

Yours faithfully,



(Dr. Pradeep Halder)

Deputy Commissioner (Immunization)

Copy to:

1. State Immunization Officer, All States/UTs
2. PPS to AS & MD
3. PPS to JS (RCH)
4. DC (CH&I)
5. All Partners

GUIDELINES FOR USE OF OPEN VIAL IN IMMUNIZATION PROGRAM

- 1) This opened vial policy applies to multi-dose vials of the DPT, TT, Hepatitis B, Oral Polio Vaccine (OPV) and Liquid Pentavalent (where applicable). **This policy does not apply to Measles, BCG, Japanese Encephalitis (JE) vaccines.**

CONDITIONS THAT MUST BE FULFILLED FOR THE USE OF OPEN VIAL POLICY:

- 2) **Use** the DPT, TT, Hepatitis B, Oral Polio vaccine (OPV) and Liquid Pentavalent (DPT+HepB+Hib) (where applicable) vaccines opened in a fixed or outreach session can be used at more than one immunization session up to four weeks provided that:
 - a) The expiry date has not passed.
 - b) The vaccines are stored under appropriate cold chain conditions both during transportation and storage in cold chain storage point.
 - c) The vaccine vial septum has not been submerged in water or contaminated in any way.
 - d) Aseptic technique has been used to withdraw all doses.
 - e) The vaccine vial monitor (VVM), has not reached the discard point.
- 3) **Discard** vaccine vial in case any one of the following conditions is met:
 - a) If expiry date has passed.
 - b) VVM reached discard point (for freeze dried vaccine, before reconstitution only) or Vaccine vials without VVM or disfigured VVM.
 - c) No label or partially torn label or writing on label is not legible.
 - d) Any vial thought to be exposed to non-sterile procedure for withdrawal.
 - e) Open vials that have been under water or vials removed from a vaccine carrier that has water.
 - f) If vaccine vial is frozen or contains floccules.
- 4) Health workers must be able to distinguish between vials that can be used in subsequent sessions and vials that must be discarded. Training and supervision materials should be revised to reflect the policy change.

COLD CHAIN MAINTENANCE AND VACCINE DISTRIBUTION

- 5) Maintain temperature of ILR between 2⁰ to 8⁰C for storage of vaccines & diluents and monitor temperature twice daily regularly.
- 6) Note the manufacturer, batch and expiry date of the vaccine and diluent in the stock register.

- 7) Proper recording and reporting of vaccine distribution and usage has to be ensured.
- 8) Keep stock upto date, don't over-stock or under-stock vaccines and diluents.
- 9) Multi-dose vials from which at least one dose has been removed may be at risk of contamination of the vial septum. These vials should therefore, never be allowed to be submerged in water (from melted ice for example) and the septum should remain clean and dry. NOTE: Well-sealed conditioned icepacks should be used in vaccine carriers and water should not be allowed to accumulate where the vials are stored. Vaccine vials must be transported in a plastic zipper bag.
- 10) Keep the "returned, partially used" vials in a separate box, and label it accordingly.
- 11) Observe earliest expiry first out (EEFO) policy for issuing vaccines. If the vaccines are of same expiry date, the partially used vaccine vials should be re-issued. The vial opened earlier, as recorded on the vial label, should be issued first.
- 12) Contingency plan has to be in place in case of any exigency like power failure, equipment breakdown, etc.

AT AND DURING THE IMMUNIZATION SESSION

- 13) Inspect for and discard vaccine vial with visible contamination (i.e. checking for any change in the appearance of vaccine or any floating particles) or breaches of integrity (e.g. cracks, leaks).
- 14) All vaccines vials must be marked with date & time of opening at first use.
- 15) Note the manufacturer, batch and expiry date of the vaccine and diluent in the tally sheet.
- 16) Always pierce the septum with a sterile needle for drawing vaccine from the multi-dose vials used. Except oral polio vaccine which is given 2 drops orally, cap needs to be closed after each use.

AFTER IMMUNIZATION SESSION IS OVER




- 17) Ensure that the vaccine vials are returned inside a vaccine carrier from the session site to cold chain point immediately after session ends, using the alternate vaccine delivery mechanism in the reverse cold chain.
- 18) Under no circumstance the vaccine carrier/vaccines will be kept in the field, in case of such an event, the vaccines in such vaccine carriers should be discarded and not used for subsequent sessions.
- 19) Storage of vaccines at any place other than a designated cold chain point will not be allowed. No vaccines should be stored at ANM/LHV or other health worker/ASHA house.

SPECIFIC ATTENTION WHILE IMPLEMENTING OPEN VIAL POLICY

20) This policy is NOT applicable to opened reconstituted vials of Measles, BCG and JE vaccine, which will be used as per following instructions and discarded immediately after use:

- a) Before reconstitution check that vaccine is within expiry date and the VVM has not reached the discard point. Reconstitute the vial ONLY with diluent provided by manufacturer for that batch of the vaccine.
- b) Date and time of reconstitution must be mentioned on the label vial at the beginning of session.
- c) Reconstituted vials will only be used for a single session; they will not be carried from one session to another, even if the session is close by.
- d) BCG and Measles must be discarded within **four hours** of reconstitution or at end of session whichever is earlier.
- e) JE to be discarded after **two hours** of reconstitution or at end of session whichever is earlier.

21) All vaccines are supplied with VVM. Please note that the VVM has only three status ie (i) start point (ii) end point (iii) end point exceeded. The vaccine has to be use before reaching the end point.

Start point		Square lighter than circle. If the expiry date has not passed, USE the vaccine.
End point		Square matches the circle. Do NOT use the vaccine.
End point exceeded		Square darker than the circle. Do NOT use the vaccine.
